

Adenovirus Antigen Rapid Test Cassette (Colloidal Gold)

Cassette

Package Insert

A lateral flow immunochromatographic assay for the qualitative detection of Adenovirus antigen (Adeno Ag) in human feces. For professional in vitro diagnostic use only.



In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box, 10T/box, 20T/box, 25T/box, 40T/box, 50T/box

INTENDED USE

The Adenovirus Antigen Rapid Test Cassette (Colloidal Gold) is a lateral flow immunochromatographic assay for the qualitative detection of Adenovirus antigen in human feces. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Adenovirus. The test is recommended for professional use only. All results must be interpreted together with other clinical information available to the physician.

SUMMARY

Adenovirus is one of the main causes of acute gastroenteritis, especially in children under the age of two years. Adenovirus have been identified in almost 50% of the feces of children with gastroenteritis. Adenovirus infections occur frequently during the winter months. Gastroenteritis from enteric viruses can be mortal in risk populations such as children, the elderly or immunosuppressed individuals. Characteristic symptoms include vomiting, hydrodiarrhoea for between 3 and 8 days, high temperature and stomach pains. Adenovirus transferred via the fecal-oral route are eliminated in large quantities into the intestine, so that hospital-borne infections from Adenoviruses are regarded very seriously, particularly in baby stations and paediatric clinics, and are difficult to control. Early and reliable detection so that adenoviruses can be recognized and further infections avoided is therefore very important. ELISA technology has good simplicity, rapidity, sensitivity and specificity. Unfortunately this test procedure is time consuming. Latex test is less sensitive than ELISA, and it requires fecal material manipulation and more or less skills to interpret results. The Adeno Ag Rapid Test is an immunochromatographic assay that detects the presence of adenovirus antigen in stool specimens. The test is simple and easy to perform and the test results can be visually interpreted within 10-15 minutes.

PRINCIPLE

The Adeno Ag Rapid Test cassette contains a membrane strip, which contains a monoclonal antibody conjugated with gold particles and directed against specific human genus-specific Adenovirus antigens. In this test the specimen is first treated with an extraction solution to extract Adenovirus antigens from the feces. Following extraction, the only step required is to add the extract to the reaction device. As the sample flows through the test membrane, the colored particles migrate. If increased level of Adenovirus Antigen is present in the specimen, within the test window, a red colored conjugated immunocomplex formed test line (T) will appear and it indicates a positive result. If the test line (T) does not appear, it indicates a negative result. The test contains an internal control line (C) which should appear as a red line regardless of color development on the test line (T). Otherwise, the test result is invalid and the assay shall be repeated with another test device.

MATERIALS PROVIDED

Test devices. Each test cassette is packed in a foil pouch with a package of desiccant.

Extraction diluents

Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or Timer

A clean container for holding stool specimen

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

Store the kit in cool and dry places at a temperature between 2-30°C. **Do not freeze.** The shelf-life of the kit under these storage conditions is 24 months. Care should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation.

SPECIMEN COLLECTION AND PREPARATION

Stool samples must be taken as soon as the symptoms appear. Viral particles decrease in number after one week, making the diagnosis more difficult. The samples should be collected in containers that do not contain media; preservatives, animal serum or detergents as any of these additives may interfere with the Adeno Ag Test. Specimens may be stored at 2-8°C for 1-2 days. For long-term storage of specimens, -20°C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

ASSAY PROCEDURES

Test device, patient's specimens, and controls should be brought to room temperature (10-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from its protective pouch. Label the device with patient or control number.
2. Remove sample probe from preparation device and coat liberally with fecal sample. Replace probe in vial and shake to disperse solid material. For liquid or semi-solid stools, 100µL of stool may be added using an appropriate pipette.
3. Allow the mixture to stand for 1-2 minutes.
4. Snap top from preparation device and invert. Add 3-4 drops to the sample well of the test cassette.
5. Start the timer. Result can be read in 10-15 minutes. **Don't read result after 20 minutes.**

INTERPRETATION OF RESULTS

(Please refer to the illustration)



Negative:

One red line appears in the control line region (C). No line appears in the test line region (T).

Positive: Two distinct red lines appear. One red line should be in the control line region (C) and another apparent red line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of adenovirus antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

Invalid: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE

To have clinical study on the sensitivity and specificity of Adeno Ag rapid test relative to a leading commercial rapid test, 520 samples from patients were studied. The results are shown in below table 1.

Table 1:

Relative Evaluation Result		Commercial Adeno Ag rapid test		Total Results
		Positive	Negative	
Adeno Ag Rapid Test	Positive	65	5	70
	Negative	3	447	450
Total Results		68	452	520

The study demonstrated below results for Adeno Ag Rapid Test:

Sensitivity = $65/(65+3) \times 100\% = 95.6\%$

Specificity = $447/(5+447) \times 100\% = 98.9\%$

Accuracy = $(65+447)/(65+3+8+452) \times 100\% = 98.5\%$

PRECISION

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. The specimens were correctly identified >99% of the time.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance

LIMITATIONS OF THE ASSAY

1. The test should be used only for the detection of Adenovirus antigen in fecal samples.
2. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result.
3. The correlation of the results with other techniques (ELISA) was excellent. However, interferences in the performance of the tests should not be excluded.
4. No cross-reactions with other viruses or substances were observed during the evaluation of the test. A negative result does not totally exclude a possible Adenovirus infection. The significance of the results must be evaluated in relation to the patient's clinical symptoms.

Code:GKPD040-1 Effective date: May 28, 2024

Index of Symbols

	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
	Temperature scope within which the product is reserved		Batch number
	Catalog #		Tests / box
	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		



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